DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER
2003-DT-12

March 4, 2003

Mr. Fritz Heerdt
President
Innovative Products Unlimited, Inc.
4351 W. College Ave.
Suite 505
Appleton, WI 54914

Dear Mr. Heerdt:

Investigator George G. Calafactor conducted an inspection of your medical device manufacturing firm, located in Niles, Michigan, dated May 28 through June 3, 2002. At the conclusion of that inspection, Investigator Calafactor issued to Mr. Timothy P. Belanger, Business Manager, a FORM FDA-483, list of Inspectional Observations (copy enclosed). The inspection revealed several serious violations of the Federal Food, Drug, and Cosmetic Act, (the Act).

Our inspection found that your firm is operating in violation of the Medical Device Reporting (MDR) Regulation, Title 21, Code of Federal Regulations (CFR), Part 803, and section 519 of the Act, in that you have failed to file adverse event reports as required by Subpart E, the Manufacturer Reporting Requirements of 21 CFR 803. This causes your medical device products to be misbranded within the meaning of Section 502(t)(2) of the Act. Specifically, you failed to promptly report to the FDA the results of a review and investigation of nine MDR-reportable complaints that were reported to your firm concerning your devices, as required by 21 CFR 803.50 .

Our inspection also found that your firm is operating in violation of the Quality System Regulation, Title 21, CFR Part 820, in that the methods used in, or the facilities used for, the design, manufacturing, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use, are not in compliance with that regulation. Because of these violations, the medical devices, manufactured by your firm, are adulterated within the meaning of Section 501(h) of the Act. Specific Quality System violations include:

1. Failure to establish an effective management control system as required by 21 CFR 820.20. For example:

a. No management representative has been appointed.
b. No quality policy has been implemented or documented.
c. No quality plan has been defined and established.
d. Management reviews have not been conducted.
e. Quality system procedures have not been defined.

2. Failure to establish quality system procedures as required by 21 CFR 820.20(e) to address each of the operations listed below.

a. No quality audit procedures, as required by 21 CFR 820.22.
b. Regarding the Class II devices manufactured by your firm, no design control procedures as required by 21 CFR 820.30(a).
c. No procedures to control changes to documents required by the Quality System Regulation, as required by 21 CFR 820.40(b). For example, there are no procedures for changes to product specifications, methods, processes, or procedures.
d. No procedure to control nonconforming product, as required by 21 CFR 820.90. For example, there are no written procedures for dealing with products that do not conform to specifications, including instances in which products are reworked because they have failed to meet specifications.
e. No procedure for implementing corrective and preventative actions, as required by 21 CFR 820.100.
f. No procedures for acceptance of components, manufacturing materials, in-process devices and finished products as required by 21 CFR 820.80, and for identifying whether or not these products conform to acceptance criteria, as required by 21 CFR 820.86. For example, there are no written procedures for acceptance testing of any gurney product models' incoming components, in-process products, and finished products.
g. No procedures to control labeling activities, as required by 21 CFR 820.120. For example, while you maintain master labels for your gurney models, these master labels lack signatures and dates to document that they have been reviewed and approved, and there are no written procedures for examining the incoming labeling of all gurney models against approved master labels to ensure that the labeling is accurate. There are also no written procedures for examining finished product labeling for gurneys, including labels generated using software maintained by your company.
h. No procedures for control of the production processes, as required by 21 CFR 820.70. For example, there are no documented instructions, standard operating procedures, and methods that define and control the manner of production to ensure that devices conform to specifications. There are no documented indications that the "master" gurney, which is utilized as a guide during production of all gurneys, conforms to the gurney device master records. No blueprint drawing exists for the USG 1200 Gurney – Heavy Duty Shower w/Pan. Additionally, the gurney device master records that are on hand in your

facility are not utilized by production and quality control personnel during the manufacture of the gurney products or during quality control acceptance testing of gurneys.

i. No procedures to identify training needs, as required by 21 CFR 820.25(b).

3. Failure to provide for training to permit employees adequately to perform their assigned responsibilities, as required by 21 CFR 820.25 (b). For example, you have not provided training for management employees to assure proper application of the Quality System Regulations.

4. Failure to document employee training as required by 21 CFR 820.25(b). For example, although interviews with management indicate that production and quality control personnel involved in manufacture and quality control activities for the gurney products have received on-the-job training, there is no documentation of this training.

5. Failure to have conducted any quality audits as required by 21 CFR 820.22.

6. With regard to the Class II medical devices manufactured by your firm, failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30. For example, you have not maintained a design history file, and there is no documentation available that indicates if design control activities were conducted for the Model USG 1200 Heavy Duty Shower w/Pan Gurney that was first manufactured in July 1999.

7. Failure to define complaint handling procedures to ensure that all complaints are evaluated to determine whether the complaint should be filed as a Medical Device Report, as required by 21 CFR 820.198(a)(3). Your written complaint procedures do not assure that complaints are properly handled. There is no evidence that product complaints have been evaluated to determine if they represent MDR events or have been investigated by your firm. As noted above, you have failed to file reports of several reportable events. In fact, we have never received an MDR from you, although we have 45 records of adverse events involving your devices reported by user facilities and voluntary reporters. Examples of complaints found in your files that have not been adequately investigated include the 12/12/2001 complaint pertaining to an SCC 250 Shower Commode Chair, serial number 8895C and the 6/6/2000 complaint pertaining to a lawsuit involving a misassembled walker.

8. Failure to maintain complete complaint files as required by 21 CFR 820.198(a). Specifically, at least 10 of 18 complaint files reviewed did not contain the "Official FDA Compliant Complaint Forms" that your firm indicates it uses to document complaint information including the name of the complainant, date of complaint, nature and details of complaint, evaluation of need for investigation, and results of any investigation.

9. Failure to maintain device history records as required by 21 CFR 820.184. For example, finished devices were released for distribution although there was:

a. No documented review to assure the devices were made in accordance with the device master record.
b. No indication that the devices met defined specifications.
c. No record of rework performed when manufactured devices initially failed to meet specifications.
d. No record of the actual label and labeling.
e. No record of the manufacturing dates.

10. Failure to ensure that device packaging and shipping containers are designed and constructed to protect the device during processing, storage, handling, and distribution, as required by 21 CFR 820.130. There is no documentation indicating that you have evaluated your device containers as required by this regulation.

11. Failure to conduct supplier evaluations as required by 21 CFR 820.50(a). For example, there are no purchasing control documents for the supplier, [redacted].

The above is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure adherence to each requirement of the regulations. Other Federal agencies are advised of the issuance of all Warning Letters about medical devices so they may take this information into account when considering the award of contracts. Additionally, pending PMA applications may not be approved until quality systems violations are corrected.

We request that you take prompt action to correct these violations and to ensure that your device manufacturing operations are in full compliance with the Act and regulations promulgated thereunder. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice, such as seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of any steps you have taken, or intend to take, to bring your firm into compliance. If corrective actions cannot be completed within 15 working days, please state the reason for the delay and the time frame within which the corrections will be implemented.

Your response should be directed to Melvin O. Robinson, Compliance Officer, at the above address.

Sincerely yours,

Joann M. Givens
Director, Detroit District